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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,839	03/30/2004	Theoharis C. Theoharides	51275/151	3048
28538	7590	09/14/2007	EXAMINER	
DR. MELVIN BLECHER 4329 VAN NESS ST., NW WASHINGTON, DC 20016			HAGOPIAN, CASEY SHEA	
			ART UNIT	PAPER NUMBER
			1615	
			MAIL DATE	DELIVERY MODE
			09/14/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/811,839

Applicant(s)

THEOHARIDES, THEOHARIS C.

Examiner

Casey Hagopian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 39-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Receipt is acknowledged of applicant's Preliminary Amendment filed 8/19/2004.

Claims 1-38 have been cancelled. Claims 39-44 are currently pending.

### ***Priority***

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

This application is claiming the benefit of prior-filed nonprovisional application No. 09/056,707 under 35 U.S.C. 120, 121, or 365(c). Copendency between the current application and the prior application is required. Since the applications are not copending, the benefit claim to the prior-filed nonprovisional application is improper. Applicant is required to delete the reference to the prior-filed application from the first sentence(s) of the specification, or the application data sheet, depending on where the reference was originally submitted, unless applicant can establish copendency between the applications.

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the

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requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 09/771,669, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Specifically, application '669 does not have support for the limitations, "protecting against the inflammatory components of pelvic endometriosis" and "hydroxyzine". PCT/US02/00476 is a CON of application '669, thus the PCT also lacks support for the instant claimed invention.

Accordingly, applicants are not afforded priority to applications PCT/US02/00476, 09/771,669 and 09/056,707. Therefore, without evidence to the contrary, the filing date of 3/30/2004 is also deemed the priority date for the instant application.

### ***Claim Objections***

Claim 39 is objected to because of the following informalities: a "." is missing at the end of the claim. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 39-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

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which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.** There is no teaching of "protecting against the inflammatory components of pelvic endometriosis" ; the subject matter is not properly described as filed. The specification states, "[p]elvic inflammatory conditions, such as presents in endometriosis, can also be treated with the inventive compositions" (paragraph 0034) and as such it is suggested that applicant incorporate the same language drawn to "treating" or "treatment" in the claim. Applicant is invited to identify the portion of the specification that teaches said limitation, as the examiner has not been able to locate the applicable disclosure. The claims within this rejection are examined as written by the applicant; at this time new matter must be considered as part of the claimed subject matter.

Claim 42 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.** There is no teaching of the particular combination of ranges claimed including "50-3000 mg of chondroitin sulfate and quercetin or myricetin, 25-100 mg of hydroxyzine, and 150-600 mg of olive kernel extract" ; the subject matter is not properly described as filed. Applicant is invited to identify the portion of the specification that teaches said limitation, as the examiner has not been able to locate the applicable disclosure. The claims

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within this rejection are examined as written by the applicant; at this time new matter must be considered as part of the claimed subject matter.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 43 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 43 recites the limitation "the composition of claim 43" in the last line of the claim. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindsberg et al. (US 2006/0210551 A1).

Lindsberg teaches compositions comprising a mast cell degranulation-blocking agent and/or a mast cell activation-blocking agent (Abstract). Lindsberg teaches that a preferable mast cell degranulation-blocking agent is a histamine-1 receptor antagonist including hydroxyzine (paragraphs 0036-0037). Lindsberg further teaches other agents that inhibit mast cell secretion and proliferation including flavonoids such as quercetin optionally in combination with chondroitin sulfate (paragraph 0038).

A person of ordinary skill in the art would have been motivated to combine hydroxyzine, quercetin and chondroitin sulfate because Lindsberg teaches all of the agents to be used for the same purpose (i.e., art recognized equivalents). A practitioner would have reasonably expected a composition effective in blocking mast cell granulation.

"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose .... The idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Therefore, in Lindsberg, it would have been prima facie obvious to a person of ordinary skill in the art at the time the claimed invention was made to have combined

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hydroxyzine, quercetin and chondroitin sulfate in order to form a new composition effective in blocking mast cell granulation.

It is noted that claims 39-42 are composition claims and as such any intended use recitation such as "for protecting against the inflammatory components of pelvic endometriosis" in claim 39 does not alone show patentable distinction. A recitation of intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. In other words, if the prior art structure is capable of performing the intended use, then it meets the claim.

### ***Conclusion***

All claims have been rejected; no claims are allowed.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at 571-272-0588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

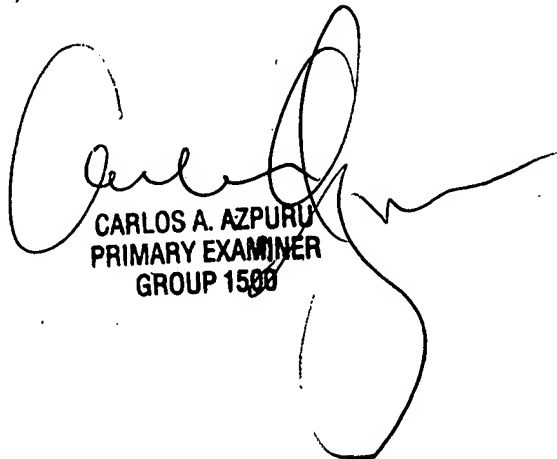


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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Casey Hagopian/

Casey Hagopian  
Examiner  
Art Unit 1615



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